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09/429,331	10/28/1999	LISA A. PAIGE	PAIGE=1D	5796
1444	7590	09/22/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			WESSENDORF, TERESA D	
		ART UNIT	PAPER NUMBER	
			1639	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/429,331	PAIGE ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 July 1994.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-134 is/are pending in the application.
4a) Of the above claim(s) 4,5,10,15,19-22,28-35,40-42 and 44-134 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-3,6-9,11-14,16-18,22-27,35-39 and 43 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-2, 3 (to the extent of the elected combinatorial library), 6-9, 11-14, 16-18, 22 (based on the elected species), 23-27, 35 (with respect to the elected species), 36-39 and 43 are acknowledged.

Claims 4-5, 10, 15, 19-21, 22 (as to the non-elected species), 28-34, 35 (with respect to the other non-elected species) 40-42 and 44-134 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse.

Applicants' election of the species is acknowledged. The elected species are as follows:

- A. Estrogen receptor beta as the receptor.
- B. Tamoxifen for the ligand.
- C. 4-OH tamoxifen-liganded receptor as the Reference Conformation.
- D. Oligopeptide for combinatorial library.
- F. In-vitro screening
- G. Estradiol as the reference substance.

H. Peptide family as outlined in table 10 as the panel species. (This has been limited to the LXXLL family as claimed in claim 23).

Status of Claims

Claims 1-134 are pending

Claims 4-5, 10, 15, 19-21, 22 (as to the non-elected species), 28-34, 35 (with respect to the other non-elected species) 40-42 and 44-134 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 1-2, 3 (to the extent of the elected combinatorial library), 6-9, 11-14, 16-18, 22 (as to the elected species), 23-27, 35 (with respect to the elected species), 36-39 and 43 are under examination.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a ***single paragraph*** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities:

1). There are no sequence identifiers for the different, numerous sequences given in the Tables. Applicants are requested to check for the other sequences in the specification without any Seq. ID. No.

Appropriate correction is required.

The lengthy (jumbo) specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic).

Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the entire claimed process steps of e.g., claims 1-2. The specification does not provide an antecedent basis for the step-by-step process of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-9, 11-14, 16-18, 22-27, 35-39 and 43 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of the process steps, as claimed. There is no disclosure as to how a method in which a compound can be predicted to modulate a receptor using the claimed method. The scope of the claimed invention appears to be speculative. Likewise, the examples present what appear to be proposed studies as to how the experiments or invention should proceed. There appears to be no actual and specific Examples (experiments) done for the process steps. The

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process steps therefore are based on predictions and assumptions. The specification and the claims are replete with numerous prophetic statements and the actual exemplification is nil. One skilled in the art would therefore have not deemed applicants' prophetic statements to a reference compound to a known receptor to be predictive to an unknown nuclear receptor. In a highly unexplored and very unpredictable art, it is not seen how such prediction or assumptions can be made. The high unpredictability in the art is evident from the Valadon (J. Mol. Biol.) reference. Valadon discloses at e.g., page 15 that the binding of a receptor to a specific peptide i.e., hexapeptides bearing motif in a (hexa)mer library was prevented by the amino acid residues of the linkers surrounding the (hexa)mer insert and that a larger insert is required. It is also likely that the excess of certain phage like in the (hexa)mer library was due to a bias that arose during reamplification of the library that selected for phage with a particular growth advantage. The screening of the biased short hexapeptide library allowed the isolation of only a few clones having aberrant sequences but identified a motif that was probably only transiently present at the beginning of the screening of the (deca)mer

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library and would otherwise have been lost. Also, see the similar observations made by Oliphant (Methods in Enzymology), particularly at page 579, last paragraph and the paragraph bridging pages 581-582. The amount of direction or guidance presented in the specification is practically nil. There is no working example that guides or directs a skilled artisan to a detail description of the invention. Working example might not be required for predictable art such as mechanical. In a highly unpredictable art such as peptide library one cannot predict the effect of even a slight change to any of the components in the method. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with no or if any, little assurance of success. See University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003). Furthermore, the claims cover a huge scope of undefined variables. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Col, 43 USPQ 2d

1398, 1405 (1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). It is not sufficient to define it solely by its principal biological property, . . . because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-9, 11-14, 16-18, 22-27, 35-39 and 43 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The process step (a) contains numerous and what appears to be unnecessary steps that render the claim confusing. For example, it is not clear as to the essentiality of determining the modulating activity of a compound in a panel when the compound is already known to bind to a receptor. It is further unclear whether the language "were the effect of a plurality of reference substances, known to modulate the biological activity

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of the receptor, on the binding of each member of the panel is known" is an independent and separate step from the preceding process step. The claims recite for too numerous unrelated components. The used of different terminologies e.g., "compound", "test substance" and "plurality of members" to mean the same or different things make the claims confusing. (Claims 1 and 2).

B). Claim 3 recitation of "ligand" lacks antecedent basis of support from the base claim 1 which does not recite a ligand.

C). Claim 14 recitation of "the first combinatorial library" lacks antecedent basis of support from the base claim 1.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 9 and 23 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 6 of prior U.S. Patent No. 6,617,114 ('114). This is a double patenting rejection.

The instant claimed method is the same or else are so close in content with the '114 Patent that they both cover the same thing, despite a slight difference in wording.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-9, 11-14 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2 and 6 of U.S. Patent No. 6,617,114 ('114 Patent). This is a double patenting rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the nuclear

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receptor of the '114 Patent would be covered by the instant broad receptor. The instant claimed process steps are so close in content or nearly the same with the '114 Patent that they both cover nearly the same thing, except the components appear to be called by different terminologies.

Claims 1-3, 6-9, 11-14 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over the '114 Patent.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For

applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claimed method covers nearly the same method in the '114 Patent except that the '114 Patent recites that the peptide in the library is characterized by Seq. ID. No. 121. However, this sequence is recited in claim 23.

Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-29, 32, 35 and 37 of each of the copending Application Nos. 09/860,688; 10/332,708 and 10/346,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of these copending applications recites nearly the same process steps as the instant process steps. Each of the copending applications however, incorporates the steps of expressing the library in a cell. However, it would have been obvious to one having ordinary skill in the art to use cells to express the library since this is the conventional method to screen a library of peptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6-7, 11-14, 18 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kauvar et al (USP 5,587,293) (I) or Kauvar et al [Current Biology (II)]. [As best the claimed invention can be interpreted.]

Kauvar et al (I) discloses at col. 2, line 60 up to col. 3, line 60 a method comprising preparing a reactivity binding profile of the target receptor with respect to a "training set" of compounds (plurality of members in a panel, as claimed), preferably having characteristics which are systematically diverse. The training set might include, for example, ten different compounds, which will have varying degrees of affinity for the target receptor. Thus, the target receptor profile will show a set of varying affinities with these compounds. Rather than test additional candidate ligands with respect to the target receptor itself, a "surrogate" is artificially created by testing the reactivity of this same set of ten training compounds against another panel to which the training set also shows varying degrees of reactivity. This might be called a reference receptor panel. Each compound in the training set will therefore show a pattern of reactivities with respect to this second panel. This results in a two-dimensional matrix wherein the level of reactivity of each member of the training set with respect to each member of the receptor panel

is recorded. The level of reactivity of each member of the reference panel with each of the training compounds is thus simultaneously recorded in an orthogonal dimension. Each one of the "reference receptors" will show a different profile with respect to the training set than did the actual target receptor. However, some computational combination, preferably a linear combination, of the these reference receptor profiles will generate a profile which matches as closely as possible that obtained from the target receptor itself. That optimal approximation constitutes a surrogate for the target receptor. The formula, which results from the computation with respect to the reference receptors is used to estimate reactivities for newly tested compounds. Empirically, such surrogates have good predictive power when applied to ligands outside the training set. A library of ligand profiles against the reference panel can thus be searched computationally with results comparable to a direct physical screen of the ligands. Thus, for each compound subsequently tested, reactivity against each member of the reference panel is obtained and the formula derived from the training set is applied to obtain a predicted value with respect to the target receptor. Rather than directly testing the reactivity of a candidate compound with a target, it is possible instead to test its reactivity with respect to a panel of

readily available reference receptors, apply the formula to the results, and predict what would have happened had the target receptor itself been used. The larger the library of stored ligand profiles against a reference set, the larger the increase in efficiency for screening by surrogate.

Kauvar (II) basically discloses the same method as Kauvar (I). Kauvar discloses at page 108, Table 1 the compound library (reference substance) including taxol.

Claims 1-3, 6-7, 11-14, 18 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein et al (6,255,059).

Klein discloses at col. 2, line 55 up to col. 3, line 34, an assay method for screening and identifying compounds that specifically interact with and modulate the activity of a cellular receptor or ion channel. The assay enables rapid screening of large numbers of polypeptides in a library to identify those polypeptides which agonize or antagonize receptor bioactivity. The method comprises using a library of recombinant cells, each cell of which include (i) a target receptor protein whose signal transduction activity can be modulated by interaction with an extracellular signal, the transduction activity being able to generate a detectable signal, and (ii) an expressible recombinant gene encoding an exogenous test polypeptide (test substance of unknown activity, as claimed)

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from a polypeptide library. By the use of a variegated gene library, the mixture of cells collectively express a variegated population of test polypeptides. The polypeptide library includes at least 10 different polypeptides, though more preferably at least 10-10⁷ different (variegated) polypeptides. The polypeptide library can be generated as a random peptide library, as a semi-random peptide library (e.g., based on combinatorial mutagenesis of a known ligand). Klein at col. 8, lines 55-64 discloses another embodiment of a method in which the peptide library can be screened for members, which potentiate the response to a known activator of the receptor. In this respect, surrogate ligands identified by the present assay for orphan receptors can be used as the exogenous activator, and further peptide libraries screened for members, which potentiate or inhibit the activating peptide. Alternatively, the surrogate ligand can be used to screen exogenous compound libraries, which, by modulating the activity of the identified surrogate, will presumably also similarly affect the native ligand's effect on the target receptor. The surrogate ligand can be applied to the cells. In col. 17, lines 42-60 Klein disclose the target receptor as a nuclear receptor such as estrogens, progesterone and etc. Klein discloses at col. 35, lines 17 up to col. 36, line 49 the peptide library is derived to express a

combinatorial library of polypeptides, which are based at least in part on a known polypeptide sequence or a portion thereof (not a cDNA library). The polypeptide(s) which are known ligands for a target receptor can be mutagenized by standard techniques to derive a variegated library of polypeptide sequences which can further be screened for agonists and/or antagonists (receptor modulating activity of a compound, as claimed.) For example, the surrogate ligand identified for FPRL-1, e.g., the Ser-Leu-Leu-Trp-Leu-Thr-Cys-Arg-Pro-Trp-Glu-Ala-Met (SEQ ID NO: 4) peptide, can be mutagenized to generate a library of peptides with some relationship to the original tridecapeptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-9, 11-14, 16-18, 22-27, 35-39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kauvar (I or II) in view of Kushner et al (USP 5,723,291) or applicants' disclosure of known prior art.

Claims 1-3, 6-7, 11-14, 18 and 35 as rejected over Kauvar is discussed above. Kauvar does not disclose the receptor as a nuclear receptor i.e., estrogen. However, Kushner discloses at col. 5, lines 33-35 that estrogen receptors activate transcription by interaction with another response element, the AP 1 binding site, instead of binding to EREs. This AP1 mediated pathway, referred to as the indirect estrogen response, may account for much of the agonistic properties of tamoxifen and other putative antiestrogens.

Applicants' disclosure at page 4 up to page 7 discloses the known family of nuclear receptors e.g., estrogen. The estrogen receptor resides in the nucleus of target cells where it is associated with an inhibitory heat shock protein complex. Upon binding ligand, the receptor is activated. This process permits the formation of stable receptor dimers and subsequent interaction with specific DNA response elements located within the regulatory region of target genes. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to employ in the method of each of Kauvar, estrogen as taught by Kushner or the known prior art disclosed by applicants in the disclosure. One would be motivated to pick estrogen receptors as target in screening assays for its role in transcription factor binding i.e., effect on cancer cells. Also, the advantage described by applicants' disclosure would provide one more motivation. Furthermore, it would be within the ordinary skill in the art to select a particular receptor for that would suit the intended purpose.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0812. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
September 18, 2004